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ATTACHMENT 3

510(K) SUMMARY

MULTIDEX<sup>®</sup> (polyglucose) Gel contains 66.9 percent Maltodextrin NF, one percent Ascorbic Acid, USP, 10 percent glycerin USP, 22 percent Purified Water USP, and 0.1 percent sorbic acid in a multi-use container.

MULTIDEX<sup>®</sup> Gel in a multi-use container is indicated for the management of stage II, III, IV pressure sores/ulcers, venous stasis ulcers, varicose ulcers, ischemic arterial ulcers, diabetic ulcers, neuropathic ulcers, poorly healing non-neoplastic wounds/ulcers and wounds/ulcers due to trauma. These are the identical indications as the predicate device.

MULTIDEX Gel in a multi-use container contains the same ingredients as the predicate device with the addition of 0.1 percent sorbic acid as a preservative. It is packaged in a 90 gram low density polyethylene tube.